In its review of whether emergency contraception should be approved for over-the-counter sales, FDA diverged sharply from usual agency procedures and overrode the recommendations of agency scientists.

A GAO report examining FDA's decision about Plan B found that FDA officials in charge of scientific review for over-the-counter drugs and reproductive drugs disagreed with the decision and did not sign the not-approvable letter as they typically would, that evidence indicates that the decision not to approve the switch was made before scientific review was completed, and that the rationale for the decision deviated from typical FDA methodology (by raising speculative concerns regarding behavioral implications and refusing to extrapolate safety data to younger adolescents).

Another disconcerting finding in the GAO report was FDA's possible violations of federal records law. In the course of the investigation, FDA informed GAO that the Office of the Commissioner deleted emails daily and the backup files were deleted every 16 days and that the Office of the Commissioner did not retain any written correspondence, including memos.

Rep. Waxman has HHS Secretary Michael O. Leavitt to examine the records violation issue and has asked Chairman Davis for hearings on the issue. **Documents and Links**

- Letter to Chairman Davis Requesting Plan B Hearings
- GAO Report on Plan B
- Rep. Waxman's Statement on GAO's Plan B Report
- Letter to Secretary Leavitt on Plan B